REMARKS

Reconsideration of the application is respectfully requested.

Claims 1-15 and 21-35 are in the application. Through this Amendment, claims 1, 12 and 31 have been amended.

In the Official Action, the Examiner rejected claims 1-15 and 21-35 under 35 U.S.C. §103(a) as being allegedly unpatentable over Bitdinger et al. (U.S. Patent No. 5,478,316).

Bitdinger et al. is directed to an automatic self-injection device. The device includes a sleeve 28 formed to enclose needle 38. Fig. 3 shows the device prior to use with the sleeve 28 covering the needle 38. (See, col. 3, ll. 33-44). With reference to Fig. 5, the sleeve 28 covers the needle 38 prior to use, with the sleeve 28 being pressed against a patient's skin to perform use. (See, col. 5, ll. 51-59). As shown in Figs. 6-8, after use, the sleeve 28 is driven back to a shielding position, as shown in Fig. 8. (See, col. 6, ll. 22-28).

Claims 1, 12, 21 and 31 are the pending independent claims of the application. Each of the independent claims include the limitations of "a holder" and a "shield". Claim 1 states: "said shield being axially movable with respect to said holder between a retracted position, wherein said needle cannula is exposed, to an extended position, wherein a distal end of said shield extends beyond a distal end of said holder and said needle cannula is enclosed by said shield". Claim 1 further states that, "wherein said shield is initially in said retracted position, and wherein

axial movement of said barrel relative to said holder causes movement of said shield from said retracted position to said extended position." Claims 12, 21 and 31 include similar limitations. It is clear from the claims that each of the independent claims include the limitation that the "shield is initially in said retracted position". Bitdinger et al. does not provide this arrangement. Rather, in Bitdinger et al., the shield is initially in an extended position, not a retracted position. With the subject invention, a needle shield arrangement is provided which allows for a needle tip to be initially exposed to facilitate use by a practitioner in, e.g., priming a needle and inserting the needle into a patient. Bitdinger et al. does not allow for such exposure. It is respectfully submitted that claims 1, 12, 21 and 31, along with dependent claims 2-11, 13-15, 22-30 and 32-35, are patentable over Bitdinger et al.

The Examiner rejected claims 1, 12, 21 and 31 under 35 U.S.C. §112, second paragraph, as being allegedly incomplete for omitting essential structural cooperative relationships of elements. The Examiner specifically indicated that "applicant's spring is biased between the shield (59) then collar element (66) then barrel flange 24, then holder (40). Examiner is not able to see where the spring directly biases the shield (59) with the holder (40)."

In response, as set forth at MPEP §2172.01, essential matter is defined by the specification. MPEP §2164.08(c) indicates that,

> [A]n enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended. ***Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality.***

(Emphasis added).

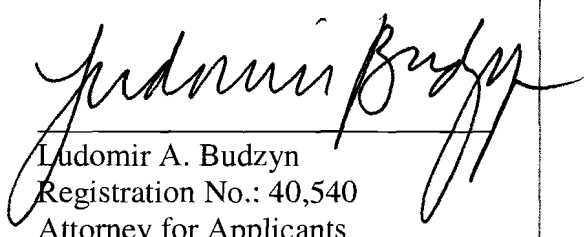
Support for the spring being within the holder, as set forth in claims 1, 12, 21 and 31, is provided in the subject application. Further, with reference to para. [0027] in the specification as originally filed (para. [0030] in the application as published), it is stated that:

> Direct engagement of the end fitting 32 or syringe flange 24 and shield, as provided in the preferred embodiment, is not necessary in such an arrangement. The operation of the device can be effected whether the shield, spring, and fitting and syringe barrel are directly or indirectly engaged, so long as axial movement of the syringe barrel causes axial movement of the shield. As discussed below, the use of an end fitting is preferred, but optional.

The Examiner stated in the rejection that the "Examiner is not able to see where the spring directly biases the shield (59) with the holder (40)." The claims do not state such a limitation – there is no requirement in the claims that the spring directly biases the shield. Claims 1, 12, 21 and 31 require that the spring be "within said holder". It is clear from the specification and the drawings of the subject application that support for the spring being within the holder is present. In addition, as set forth in the quote above, direct or indirect engagement of the spring is disclosed. There is no requirement for direct biasing, as suggested by the Examiner. It is respectfully submitted that claims 1, 12, 21 and 31 are in accord with 35 U.S.C. §112.

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicants' attorney at the number listed below.

Respectfully submitted,



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